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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,425	06/06/2007	Todd C. Zankel	30610/39385A	5100

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Marshall, Gerstein & Borun LLP (Biomarin)
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606

EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
12/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mflores@bmrn.com
lbigornia@bmrn.com
mgbdocket@marshallip.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,425	ZANKEL ET AL.	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-35* is/are pending in the application.

4a) Of the above claim(s) *35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment, response and remarks filed 24 September 2010 to the Office Action with Non-Final Rejection mailed 24 June 2010 is acknowledged and entered.

Informals

2. For the record, contrary to Applicants' assertion (See Remarks filed 09/24/2010, Page 4, Line 5) Claims 31-35, not Claims 31-34 are pending. Applicants are correct in asserting that Claim 35 is withdrawn. Accordingly, Claims 31-34 are currently under examination.

3. The instant application contains claim 35 drawn to an invention non-elected without traverse in the reply filed on 27 April 2010. A complete reply to the instant final rejection must include cancellation of nonelected claims or other appropriate action.

Claims Status

4. According to the response filed 24 September 2010, following is the status of the Claims:

- Claims 31-35 are currently pending;
- Claim 35 is currently withdrawn from consideration; and
- Claims 31-34 are currently under examination.

Withdrawals

5. Considering the Amendments and remarks filed 24 September 2010 to the Office Action with Non-Final Rejection mailed 24 June 2010, the following objections and rejections in the Office Action with Non-Final Rejection mailed 24 June 2010 are hereby withdrawn:

- Objection to specification;
- Anticipatory rejection of Claims 31-34 under 35 U.S.C. §102(b) by Amalfitano et al (2001. Recombinant human acid α- glucosidase enzyme therapy for infantile glycogen storage disease type II: Results of a phase VII clinical trial. Genetics in

Medicine, Volume 3, Number 2, Pages 132-138 Applicants' IDS filed 10/03/2008).

Double Patenting

6. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

7. Claims 31-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting (i.e., ODP) as being unpatentable over Claims 1-2 of co-pending U.S. Patent Application Number 12/182,818.

In response to the ODP rejection cited supra, Applicants acknowledge said rejection but argue that they will file "any necessary terminal Disclaimer upon notification of allowance in the co-pending", or instant application (See Remarks filed 09/24/2010, Page 4, Lines 15-20).

Applicants' above-recited argument, however, does not obviate the ODP rejection of Claims 31-34.

Applicants' arguments filed 24 September 2010 regarding the ODP rejection to Claims 31-34 as being unpatentable over Claims 1-2 of co-pending U.S. Patent Application Number 12/182,818 have been fully and carefully considered but are not persuasive for the reasons of record at pages 3 in the Office Action mailed 24 June 2010 and those discussed *supra*. Thus, the ODP rejection of Claims 31-34 as provisionally rejected under the judicially created doctrine of

obviousness-type double patenting (i.e., ODP) as being unpatentable over Claims 1-2 of co-pending U.S. Patent Application Number 12/182,818. in the Office Action mailed 24 June 2010 is maintained and adhered to.

Claim Rejections - 35 USC § 112

Rejection Under 35 U.S. C. §112, 1st Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

9. Claims 31-34 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims.

> Since the properties of the "recombinant human α - glucosidase" (i.e., rhGAA) are recited in the claims, and according to the description in the specification said rhGAA is expressed and produced in G71 cells (Specification, Page 45, Lines 22-26), wherein said G71 cells were obtained from CHO-K1-derived, END3 complementation group cell lines and further sub-cloned G71 cell lines containing different expression plasmids and designated as G715 and G71GAA2 (Specification, Page 23, Lines 10-13; said G71 cells and sub-clones thereof are essential to the invention recited in the instantly presented claims. Said G71 Cell Line must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If said G71 Cell Line is not so obtainable or available, the requirements of 35 U.S.C. §112, first paragraph may be satisfied by a deposit of said G71 Cells. The specification does not disclose a repeatable process to obtain said G71 and it is not apparent if said G71 is readily available to the public.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. " 1.801-1.809, applicants may provide

assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR ' 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

(1) The name and address of the depository;

(2) The name and address of the depositor;

(3) The date of deposit;

(4) The identity of the deposit and the accession number given by the depository;

(5) The date of the viability test;

(6) The procedures used to obtain a sample if the test is not done by the depository; and

(7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR §1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

Conclusion

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. No Claims are allowed.

12 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657
(571) 272-0923

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657